DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of International Affairs
Washington, D.C. 20201

JUN 20 2002

Tokuo Yoshida
Quality Assurance and Safety: Medicines (QSM)
Essential Drugs and Medicines Policy (EDM)
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Dear Mr. Yoshida:

I write in response to the request from the World Health Organization (WHO) for comments and information for the upcoming meeting of the WHO Expert Committee on Drug Dependence (ECDD). In particular, I refer to C.L.4.2002, which transmitted the WHO Questionnaire for Review of Dependence-Producing Psychoactive Substances by the Thirty-Third Expert Committee on Drug Dependence.

The enclosed information assembled by the U.S. Department of Health and Human Services (HHS) in response to your questionnaire is derived from many sources. In accordance with the Controlled Substances Act, the U.S. Food and Drug Administration (FDA) within HHS published the WHO notification and questionnaire on amfepramone (diethylpropion), amineptine, buprenorphine, delta-9-tetrahydrocannabinol, and tramadol in the *Federal Register* to solicit information. In response, the FDA received several comments relating to buprenorphine, delta-9-tetrahydrocannabinol, and tramadol. The FDA also received comments from four respondents regarding the adequacy of the WHO Questionnaire to provide sufficient data for assessing the abuse of these substances for the purpose of control under the international conventions. Please find enclosed all comments received in response to the *Federal Register* Notice. In addition, the enclosed information package includes information from the Drug Abuse Warning Network, the FDA's Adverse Event Reporting System, the U.S. Drug Enforcement Agency (DEA) National Forensic Laboratory Information System, and DEA's forensic laboratory database.

Also, we request, in accordance with the WHO Guidelines adopted in 1999, that the WHO forward to us the Critical Review Documents that will be developed for each of the substances under consideration by the ECDD, for our review and comment, well before the September ECDD meeting. We need to be able to offer our comments to the WHO on the Critical Review Documents, if necessary.

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In addition, we would like you to know that both HHS and outside responders find the current questionnaire to be too vague and lacking in the type of detailed questions that will solicit the most helpful data and information for the WHO in considering international scheduling for specific substances. We will approach the issue of revisions to the questionnaire in another venue. Thank you for your assistance in this matter.

Sincerely,

William R. Steiger, Ph.D.
Special Assistant to the Secretary
for International Affairs

Enclosure:
Information Package for Thirty-Third Expert Committee on Drug Dependence

WHO QUESTIONNAIRE FOR REVIEW OF DEPENDENCE-PRODUCING PSYCHOACTIVE SUBSTANCES BY THE THIRTY-THIRD EXPERT COMMITTEE ON DRUG DEPENDENCE

COUNTRY NAME: United States of America

AGENCY NAME: U.S. Department of Health and Human Services

CONTACT PERSON:

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The response should be mailed, faxed or e-mailed directly to:

Tokuo Yoshida
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1211 Geneva 27
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before ***17 May 2002***

If statistical information requested is not readily available, a brief descriptive answer would be appreciated.

Please attach copies of relevant study reports and other background information as appropriate.

If possible, answers in ***English*** *or* ***French*** *would be most appreciated.*